May 24, 2023

Magnamed Tecnologia Medica S/A
% Claudio Bacelar
Chief Business Officer and Official Correspondent
Magnamed USA
4737 NE 25th Ave - unit 205
Fort Lauderdale, Florida 33308

Re: K221634
Trade/Device Name: Oxymag - Transport and Emergency Ventilator
Regulation Number: 21 CFR 868.5925
Regulation Name: Powered emergency ventilator
Regulatory Class: Class II
Product Code: BTL
Dated: May 18, 2023
Received: May 22, 2023

Dear Claudio Bacelar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ethan L. Nyberg -S

for James Lee, Ph.D.
Division Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221634

Device Name
Oxymag - Transport and Emergency Ventilator

Indications for Use *(Describe)*
Oxymag is a controlled volume, pressure and time cycled emergency and transport ventilator. It is intended for use with infant, child, and adult patients with a tidal volume from 50 ml upwards who are in respiratory and/or cardiac arrest or respiratory distress and who require the ventilatory support.

It is intended for pre-hospital and hospital use including intra-hospital, inter-hospital and transport settings.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510k Summary

I. SUBMITTER:

MAGNAMED Medical Technology INC
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Phone: 954-980-6477

Contact Person: Claudio Bacelar
Contact Title: Chief Business Officer and Official Correspondent
Date Prepared: Apr 24, 2023

II. DEVICE

Name of device: Oxymag – Transport and Emergency Ventilator
Common or Usual Name: Electronic Transport Ventilator
Classification Name: Powered Emergency Ventilator (21 CFR 868.5925)
Regulatory Class: Class II
Product code: BTL

III. PREDICATE DEVICE

O-two e700, K141595
Manufactured by O-Two Medical Technologies Inc
This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

Oxymag provides a mixture of ambient air and oxygen at concentrations adjusted by the operator using the accurate oxygen concentration system using the venturi principle. O_2 concentration is obtained through a galvanic cell by passing gas through the sensor. In addition, it performs the control of flows and pressures in the respiratory circuit to provide the ventilation modalities appropriate to the patient's condition.

The associated accessories include:

- Power outlet 12V/3,34A
- AC cable
- Disposable respiratory circuit
- O2 extension

- Environment filters

V. INDICATION FOR USE

Oxymag is a controlled volume, pressure and time cycled emergency and transport ventilator. It is intended for use with infant, child, and adult patients with a tidal volume from 50 ml upwards who are in respiratory and/or cardiac arrest or respiratory distress and who require the ventilatory support.

It is intended for pre-hospital and hospital use including intra-hospital, inter-hospital and transport settings.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The table 1 shows the comparison between Oxymag and the predicate e700.

Table 1. Comparison table between the subject and predicate devices

	Subject Oxymag	Predicate E700 (K141595)	Discussion
Indications for use	Oxymag is a controlled volume, pressure and time cycled emergency and transport ventilator. It is intended for use with infant, child, and adult patients with a tidal volume from 50 ml upwards who are in respiratory and/or cardiac arrest or respiratory distress and who require the ventilatory support. It is intended for pre-hospital and hospital use including intra-hospital, inter-hospital and transport settings.	o_two e700, e600 and e500 are a time-cycled, volume-constant and pressure-controlled (only e700) emergency and transport ventilator designed for use in the pre-hospital, intra-hospital, inter-hospital and transport settings. It is intended for use with adult, child and infant patients with a tidal volume from 50 ml (100 ml for e500) upwards who are in respiratory and/or cardiac arrest or respiratory distress who require ventilatory support.	The indications for use is equivalent to e700. The model e700 is the only one being used as the predicate from K141595
Patient population	Infant, child, and adult patients	Adult, child, infant patients	The patient population is equivalent to e700.
Environment of use	Pre-hospital and hospital use including intra-hospital, inter-hospital and transport settings.	Pre-hospital, intra-hospital, inter-hospital and transport settings	The environment of use is equivalent to e700.

	Subject Oxymag	Predicate E700 (K141595)	Discussion
Product code	BTL	BTL	The product code is equivalent to e700.
Ventilation modes	VCV, PCV, V-SIMV, P-SIMV, CPAP/PS	A/CV, SIMV, BiLVL, CPAP and CPR	Similar to e700. Except for CPR, that is not delivered in Oxymag, the other modes have different nomenclature, but they are equivalent. ACV deliver VCV or PCV, that is equivalent to VCV and PCV. SIMV deliver volume ventilation at the set tidal volume and rate, that is equivalent to V-SIMV. BiLVL is similar to SIMV but with pressure ventilation, that is equivalent to P-SIMV. CPAP has the same nomenclature and is equivalent. Oxymag does not have CPR mode.
Breathing circuit	Dual limb, unique for all patient types	Single limb, unique for all patient types	Different to e700. Both breathing circuits are unique for all patients. The only difference is that Oxymag uses a dual limb and e700 uses a single limb. A dual limb circuit has one tube for inhalation and another for exhalation while a single limb has one tube for both inhalation and exhalation. Despite the difference, the performance of both devices is similar as demonstrated in bench test.
Exhalation valve	Connected to the equipment in the exhalation connector	Connected in the breathing circuit	Different to e700. In e700, the control of inhalation and exhalation is pneumatic. During inspiration, the exhalation valve, that is in the breathing circuit, is closed via the pressurization line from the ventilator. Oxymag electronically controls the exhalation by

	Subject Oxymag	Predicate E700 (K141595)	Discussion
			a valve connected to the equipment. Despite the difference, the performance of both devices is similar as demonstrated in bench test.
Waveforms	volume-time, pressure-time and flow- time	volume-time, pressure-time and flow- time	Waveforms are equivalent to e700 as demonstrated in bench test.
Flow sensor	Pneumotachograph	Pneumotachograph	Flow sensor is equivalent to e700.
Flow control	Proportional valves controlled by the microprocessor	Solenoid Valves activated by the microprocessor	Similar to e700. Solenoid valves have an on/off control and has a set of solenoids with different flow passages, and to deliver a flow, it opens and closes certain solenoids. Proportional valves convert a variable current or voltage signal into a proportional flow output. Despite the difference, the performance of both devices is similar as demonstrated in bench test.
Trigger Sensitivity	OFF; 1 to 15 L/min	OFF; 1 to 15 L/min	Parameter range is equivalent to e700.
Input pressure	39 to 87 psi	45 PSI to 87 PSI	Different to e700. The lower limit of Oxymag's input pressure is lower than e700, but the difference does not affect the performance of Oxymag. Oxymag delivers all ventilation parameters between 39 and 87 psi.
PSV (pressure support ventilation)	OFF; 4 to 35 cmH_2O (± 10% or ± 2 cmH_2O)	OFF, 4- 35 cmH2O (± 10% or ± 2 cmH_2O)	Parameter range is equivalent to e700.
Ventilation Frequency	5 to 60 breath/min (± 10% or ± 1 bpm)	5 to 60 breath/min (± 10% or ± 1 bpm)	Parameter range is equivalent to e700.
Tidal Volume (L)	50 to 2000 mL (±20ml or ±15%)	50 ml to 2000 mL (±20ml or ±15%)	Parameter range is equivalent to e700.
Manual ventilation/ Inspiration hold	Yes	Yes	Parameter range is equivalent to e700.
Inspiration time to expiration time ratio	1:4 to 3:1 (± 20%)	1:4 to 3:1 (± 20%)	Parameter range is equivalent to e700.

	Subject Oxymag	Predicate E700 (K141595)	Discussion
Inspiration time Ti (sec.)	0,2 to 9 s (± 20%)	0,2 to 9 s (± 20%)	Parameter range is equivalent to e700.
PEEP/ CPAP (cm H_2O)	OFF; 4 to 20 (± 10% or ± 2 cmH_2O)	OFF; 4 to 20 (± 10% or ± 2 cmH_2O)	Parameter range is equivalent to e700.
FiO_2 (%)	60 or 100 (± 15%)	60% or 100% (± 15%)	Parameter range is equivalent to e700.
Pmax	10 to 60 (± 10% or ± 2 cmH_2O)	10- 80 cmH2O (± 10% or ± 2 cmH_2O)	Different to e700. Oxymag has a more restricted upper limit.
Safety relief valve	Yes	Yes	Safety valve is equivalent to e700.
Inhalation pressure (cmH_2O)	OFF; 4 to 50 cmH_2O (± 10% or ± 2 cmH_2O)	4 - 50 cmH2O (± 10% or ± 2 cmH_2O)	Parameter range is equivalent to e700.
Apnea back up time	10 to 60 sec	10 to 60 sec	Parameter range is equivalent to e700.
Monitoring	Minute Volume, Volume Measured, Instant pressure measured, maximum inspiratory pressure, Respiratory Rate	Mve, Vte, Paw(AV), Paw(Peak), Fbpm	Similar to e700.
	Plateau pressure, PEEP, Flow, inspiratory time, expiratory time, Ratio I:E, Airway resistance, Dynamic compliance, Static compliance, FiO2, O2 consumption	None	Oxymag has the monitored parameters that e700 has and additional others, but the difference does not affect the performance of Oxymag.
Wave form displayed	Pressure and flow	Pressure and flow	Waves are equivalent to e700.
Alarms Audible/Visual & indications	Disconnection, Low airway pressure, High airway pressure, Low minute volume, High minute volume, Low minute volume, Obstruction, Low supply pressure, Apnea, Low battery,	Patient circuit disconnect, Low airway pressure, High airway pressure, Low minute volume, High minute volume, Blocked airway, Low oxygen, Apnea, Low battery, Low inhalation pressure, No Oxygen, Empty battery, Patient effort.	Significant alarms are similar to e700. Low inhalation pressure and Low airway pressure is equivalent to low airway pressure in Oxymag. No Oxygen alarm is equivalent to low supply pressure in Oxymag. Empty battery is equivalent to low battery alarm of Oxymag. Patient effort alarm is equivalent to trigger message in Oxymag.
	FiO2 below 18%, High FiO2, Low FiO2	Leak, High input pressure	Oxymag does not have leak alarm, but when there is a significant leak in the

	Subject Oxymag	Predicate E700 (K141595)	Discussion
	High PEEP, Low PEEP, AC input fail, High volume and Low volume, High r. rate, Low r. rate, Low internal temperature, High internal temperature, Flow sensor off, HW:High O2 int.		breathing circuit, the disconnection alarm is triggered. Oxymag does not have a high input pressure alarm, but it has a regulator valve, and in case of a high input pressure, the regulator valve will reduce the pressure and the performance of the device will not be affected. Oxymag has high and low FiO2 alarms that are requirements of ISO 80601-2-12 and ISO 80601-2-55. Oxymag also has FiO2 < 18% alarm that is required by ISO 80601-2-55. High PEEP , Low PEEP , AC input fail, High volume and Low volume alarms are ISO 80601-2-12 requirements. High r. rate, Low r. rate, Low internal temperature, High internal temperature, Flow sensor off and HW:High O2 int. are not standard requirement alarms, but they contribute to increase the device safety. So, the differences in the alarm system does not raise safety questions.
Accessories	- AC/DC power supply - Patient ventilation circuit - Oxygen supply hose – Environment filter	Input pressure hose, Intake filter, Power supply cord, Battery pack, Ventilator external power supply, Mounting bracket for road ambulance, Test lung and Transport ventilator carrying case	Significant accessories are equivalent to e700.
Reprocessing of Patient circuit	Single use	Single use	Patient circuit reprocessing is equivalent to e700.

Both Oxymag and e700 receive oxygen via the gas input connection. Oxymag regulates the oxygen pressure by using a regulator valve. E700 does not have a regulator valve. The valves used in e700 withstand a pressure of 100 psi, and e700 recommends a maximum input pressure of 87 psi. Oxymag also recommends a maximum input pressure of 87 psi.

To control the oxygen concentration, If the oxygen concentration adjusted is 100% in Oxymag, the proportional valve will regulate the flow and in e700 the solenoid valves will regulate the flow. If the concentration is adjusted in 60%, the venturi system will mix the oxygen with the ambient air to reach the concentration of 60% in both devices. In order to measure the concentration, Oxymag has a galvanic cell, which is different from e700 that does not have this sensor. This oxygen sensor is an additional control measure to ensure that the concentration delivered to the patient is according the adjusted and do not raise performance or safety risks.

To check the flow delivered to patient, both Oxymag and e700 have a pneumotachograph flow sensor and measure the same parameters of the patient.

In case of a high pressure in the breathing circuit occurs, both Oxymag and e700 have a safety valve to release the pressure by open the system to atmosphere.

While the breathing circuit of e700 is a single limb circuit with an exhalation valve in the breathing circuit, Oxymag uses a dual limb circuit, composed of an inspiratory and expiratory limb that are connected to the inspiratory and expiratory port. The exhalation valve is connected direct on the expiratory port of the ventilator. Despite this difference, the exhalation for both devices is similar.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for Oxymag device was conducted in accordance with the FDA Guidance “Use of International Standard ISO-10993, ‘Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process,’” September 4, 2020, and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA.

In accordance with ISO 10993-1 and FDA Guidance for Biocompatibility, the components of a ventilator are classified as externally communicating, tissue contact and duration ≤ 24 hours. Therefore, Oxymag was tested in the following tests:

- Particulate matter emission
- Volatile organic compounds
- Ozone gas analysis
- Carbon monoxide and carbon dioxide gas analysis

- Cytotoxicity
- Sensitization
- Irritation
- Systemic toxicity
- Pyrogenicity

Electrical safety and electromagnetic compatibility (EMC)
Electrical safety and EMC testing were conducted on the Oxymag. The system complies with the IEC 60601-1, IEC 60601-1-8, IEC 60601-1-12, IEC 80601-2-12, IEC 80601-2-55 for safety, IEC 60601-1-2 standard for EMC and AIM 7351732 for RFID.

Software Verification and Validation Testing
Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "major" level of concern since a failure or latent failure in the software could directly result in serious injury or death to the patient or operator.

Mechanical testing
Performance testing was conducted on the Oxymag to determine its specifications regarding ventilatory parameters, including validation with nebulizer and mask. It was performed verification of technical data, comparison between Oxymag and the predicate e700, human factors evaluation, validation of ventilatory modes, alarm system, monitored parameters, auto test, hardware and mechanical specifications.

Animal and clinical studies

There were no animal or clinical studies done for the subject device.

VIII. CONCLUSIONS

The results of the comparative performance and specification as well as bench testing demonstrate that Oxymag is substantially equivalent as the legally marketed predicate device e700.